

STATE OF MICHIGAN
DEPARTMENT OF LICENSING & REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 121884-001

United Healthcare Insurance Company
Respondent

Issued and entered
this 15th day of November 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On June 14, 2011, XXXXX (Petitioner) filed a request for an expedited external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.* In order to receive an expedited external review under PRIRA, a physician must substantiate that the Petitioner's life or health would be seriously jeopardized or the Petitioner's ability to regain maximum function would be jeopardized if an expedited review is not granted. In this case, a physician has not documented such conditions. Therefore, the Commissioner accepted the request for external review on a non-expedited basis.

The Petitioner receives health benefits under United Healthcare Insurance Company's (United) *Choice Plus* certificate of coverage and related rider. The coverage was effective July 1, 2010.

The Commissioner notified United of the external review and requested the information used in making its adverse determination. The material was received June 16, 2011. After a preliminary review of the material submitted, the Commissioner accepted the request for external review on June 21, 2011.

The Commissioner appointed an independent review organization (IRO) to analyze the medical issues in this review as required by section 11(6) of PRIRA, MCL 550.1911(6). The

IRO provided its analysis and recommendations on July 5, 2011. (A copy of the complete report is being provided to the parties with this Order.)

II. FACTUAL BACKGROUND

The Petitioner was diagnosed with the skin condition rosacea by his physician, Dr. XXXXX. He was treated for several years with Elidel 1% cream, prescribed by Dr. XXXXX.

After his health insurance became effective with United, Petitioner requested coverage for continued treatment with Elidel. Coverage was denied and, on May 16, 2011, the Petitioner filed with United a "Clinical Appeals Response Form." The form indicates that the Petitioner is "requesting Elidel for rosacea on the face." United affirmed its denial of coverage and issued its final adverse determination on May 25, 2011.

III. ISSUE

Was United's denial of coverage for Elidel cream for the treatment of rosacea consistent with the terms of the Petitioner's certificate of coverage?

IV. ANALYSIS

Respondent's Argument

In its final adverse determination of May 25, 2011, United explained its denial:

The Appeals Committee reviewed your appeal. This decision was based on Outpatient Prescription Drug Rider to your Certificate of Coverage. The Committee's determination is as follows: Per review of appeal documentation, this request does not meet the criteria for benefit coverage for diagnosis submitted; determined as unproven. Unproven services are excluded from benefit coverage.

Your request for Elidel Cream for the treatment of rosacea does not meet our criteria for coverage. The decision to deny payment authorization for the drug was based upon indications that we have determined to be proven or the FDA approved indications as listed in the manufacturer's package labeling or in evidence based literature: atopic dermatitis, eczema, psoriasis. [sic] Your prescription drug rider does not include coverage for medications when the medication is used for indications determined by us to be experimental, investigation or unproven.

Petitioner's Argument

In his June 14, 2011, request for external review the Petitioner wrote:

I have been diagnosed with an atopic dermatitis and the only medication that works for this is Elidel 1% cream. The Committee of Appeals in Transaction #W1322104003 for United Healthcare diagnosed me as having Rosacea and they haven't even seen me. My doctor, Dr. XXXXX, diagnosed me with atopic dermatitis and United Healthcare refuses to provide me with the Elidel 1% cream I requested as my doctor prescribed.

Commissioner's Review

United based its denial of coverage on its determination that Elidel cream was unproven for the treatment of rosacea. The decision was based on the following provision in the Petitioner's prescription drug rider:

Section 2: Exclusions

* * *

4. Experimental or Investigational or Unproven Services and medications; medications used for experimental indications and/or dosage regimens determined by us to be experimental, investigational or unproven. . . .

In an undated letter apparently intended for United, Petitioner's previous physician, Dr. XXXXX, wrote:

My patient XXXXX , is maintained on topical Elidel cream for treatment of his chronic inflammatory facial skin condition, ROSACEA. Patient has tried other topical medication including topical steroids without much relief of his symptoms, and seems that Elidel has worked best for his condition.

We appreciate of you reconsider your decision and approve his refills for Elidel cream.

The IRO appointed by the Commissioner analyzed the question of whether Elidel cream is unproven for the treatment of rosacea. The IRO's reviewer is a board certified dermatologist in active clinical practice who is a member of the American Academy of Dermatology and a clinical associate professor at a university-based hospital. The IRO reviewer's report includes the following conclusion and analysis:

Decision/Clinical Rationale:

It is the determination of this reviewer that the off-label use of Elidel Cream for the treatment of Rosacea is considered experimental for the treatment of the [Petitioner's] condition.

Rosacea is a complicated disease process for which the pathophysiology is still unknown, despite many theories. It is a relatively common finding and can be characterized by symptoms of facial flushing and redness with visible, telangiectatic blood vessels, and inflammatory eruptions resembling acne. The incidence of rosacea is unclear, but rosacea seems to be disproportionately common in fair-skinned individuals of Northern European and Celtic origin. It has been characterized in several subtypes which can include ocular findings, bulbous nose, dense acne, as well as others. Because of these many constellations of findings, rosacea is a clinical diagnosis.

There are a variety of treatments to control these signs and symptoms. Treatment includes identification of triggers with avoidance where possible. This is especially true of sunlight, one of the greatest instigators to this process. Sunscreen alone, despite its best efforts, is clearly necessary though imperfect.

* * *

Although there is some spotty literature conveying some success with immunomodulators such as Elidel in rosacea, these are poorly constructed studies with small sample sizes that are not powered to offer insight or validation to its use. Studies such as these are often precursors to larger studies to determine efficacy and safety of these medications as a treatment modality. To date, there are no large scale studies showing good results for the use of Elidel in the treatment of Rosacea. Moreover, there are small and better conducted randomized studies that show inefficacy of Elidel in the treatment of Rosacea. Given the criteria above and the literature review, the use of Elidel for Rosacea would not be considered a routine standard of care or an alternative off-label option.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise and professional judgment. The Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner finds that United's denial of coverage for Elidel 1% cream as unproven for the treatment of rosacea is consistent with the terms of the certificate.

In his request for review, the Petitioner asserted that Elidel cream was actually prescribed for the treatment of a different skin disorder, atopic dermatitis. However, the use of Elidel cream for atopic dermatitis was not mentioned in the final adverse determination or any other document with a date earlier than the Petitioner's June 14, 2011, request for review. The first indication that Elidel cream was prescribed for atopic dermatitis appears in a June 14, 2011, letter from Dr. XXXXX, Petitioner's current physician:

I am writing [on behalf] of my patient, Mr. XXXXX [who] has been on Elidel cream for many years. Recently his insurance company has declined coverage of that medication, because the patient was using it supposedly for acne rosacea. He is recently established with me as his primary care physician. Given his history and examination, his symptoms and exam are much more consistent with atopic dermatitis vs. eczema. I do not feel is all the patient has rosacea [*sic*]. On this basis, it is my opinion that Elidel as an appropriate treatment modality for his condition. He has had good success with this, and I see no reason to attempt to change at this point.

Under the Patient's Right to Independent Review Act the Commissioner's role is limited to determining whether an insurer correctly applies the terms and conditions of its insurance policy and any relevant requirements of state law. The Commissioner's review focuses on the insurer's final adverse determination.

In its final adverse determination dated May 25, 2011, United denied coverage of Elidel cream based on a diagnosis of rosacea. The evidence presented by the Petitioner to support a diagnosis of atopic dermatitis was submitted after United issued its final adverse determination. Because the information regarding atopic dermatitis was not a part of United's internal grievance process, it would be inappropriate to consider it in this review. Any question of the use of Elidel cream for the treatment of atopic dermatitis would have to be the subject of a new claim by the Petitioner, first to United and then to the Commissioner, should United deny coverage.

V. ORDER

The Commissioner upholds United Healthcare Insurance Company's final adverse determination of May 25, 2011. United is not required to provide coverage for Elidel cream as a treatment for rosacea.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner